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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,584	10/11/2005	Shyam S Mohapatra	USF-183XC1	4246

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EXAMINER

LL QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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04/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,584

Applicant(s)

MOHAPATRA, SHYAM S

Examiner

Q. JANICE LI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 20, 21, 23-25, 27-30 and 43-58 is/are pending in the application.
4a) Of the above claim(s) 21 and 24 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13, 15, 20, 23, 25, 27-30, 43-58 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The amendment and remarks filed on 1/10/08 are acknowledged. Claims 13, 15, 20, 21, 23-25, 27-30 have been amended, claims 31-42 have been canceled. Claims 43-58 are newly submitted.

Election/Restrictions

Applicant's election with traverse of Group III, and species election drawn to **SEQ ID No: 5** in the response filed 6/13/07 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-12, 14, 16-19, 22, 26 have been canceled. Claims 27-42 are newly submitted. Claims 31-42 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The amended claims 21 and 24 are drawn to non-elected inventions, and hence have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 13, 15, 20, 23, 25, 27-30, 43-58 are under current examination.

Specification

- I. The abstract of the disclosure is objected to because it does not commence on a sheet separate from other materials of the disclosure. Correction is required. See MPEP § 608.01(b).
- II. The amendment filed 1/10/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment

shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The SEQ ID No: 5 as originally filed is composed of 28 amino acid residues, and does not contain a glycine residue as shown in page 2 of the sequence listing as filed; whereas newly submitted SEQ ID No: 5 contains 29 amino acid residues including a glycine.

In the instant amendment to the specification on page 7, line 8, the applicant deleted the prefix "Gly" and moves it to position 73 of SEQ ID No: 5 as filed. However, the position 73 of the original SEQ ID No: 5 is Ser, not Gly.

The newly submitted SEQ ID No: 18 is based on the revised SEQ ID No: 5, and hence they also introduce new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

However, the applicant could submit a different sequence identification number for the 29aa peptide as listed in page 7, line 8 of the specification as filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15, 20, 23, 25, 27-30, 43-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13, 15, 20, 23, 25, 27-30, 43-58 are rejected under 35U.S.C. 112 first paragraph, because the specification as originally filed does not describe the invention as now claimed. The original disclosure fails to describe the newly submitted SEQ ID No: 5 as now claimed. The newly submitted SEQ ID Nos: 5, 18 are now considered to be new matter, and consequently, the claims drawn to SEQ ID No: 5 add new matter to the disclosure.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "WHENEVER THE ISSUE ARISES, THE FUNDAMENTAL FACTUAL INQUIRY IS WHETHER A CLAIM DEFINES AN INVENTION THAT IS CLEARLY CONVEYED TO THOSE SKILLED IN THE ART AT THE TIME THE APPLICATION WAS FILED...IF A CLAIM IS AMENDED TO INCLUDE SUBJECT MATTER, LIMITATIONS, OR TERMINOLOGY NOT PRESENT IN THE APPLICATION AS FILED, INVOLVING A DEPARTURE FROM, ADDITION TO, OR DELETION FROM THE DISCLOSURE OF THE APPLICATION AS FILED, THE EXAMINER SHOULD CONCLUDE THAT THE CLAIMED SUBJECT MATTER IS NOT DESCRIBED IN THAT APPLICATION". In the instant case, the applicant has revised the composition of SEQ ID No: 5 as filed, and the nucleic acid encoding such. Thus, the amendment is a departure from or an addition to the disclosure of the application as filed. Further, the pending claims encompass a genus of NHPs comprising a glycine at the amino terminus position of the peptide. However, except for the aforementioned prefix in page 7 of the specification (the meaning of the prefix is unclear), the specification as filed fails

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to specify that such a genus exists. Accordingly, the amendment introduces new matter into the disclosure.

It is noted the applicant could submit a different sequence identification number for the 29aa peptide as listed in page 7, line 8 of the specification as filed to overcome this rejection.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/319,529, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the provisional application fails to disclose SEQ ID No: 5. Thus, the priority date for the elected species, SEQ ID No: 5 has been established as the filing date of the PCT application, i.e. 9/8/03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of Claims 13, 15, 20, 21, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Lin et al* (Hum Gene Ther 1998;9:1429-38), and

as evidenced by *Lin et al* (Hypertension 1995;26:847-53), is withdrawn in view of the claim amendment and cancellation of the subject matter.

The prior rejection of Claims 20, 21, 23-25, 28-30 under 35 U.S.C. 102(b) as being anticipated by *Seidman et al* (Science 1984;226:1206-9, IDS), is withdrawn in view of the claim amendment.

Claims 13, 28, 29, 30, 43, stand or newly rejected under 35 U.S.C. 102(b) as being anticipated by *Shimkets* (US 6,013,630).

Shimkets teach a pharmaceutical composition comprising a nucleic acid sequence encoding a natriuretic hormone peptide comprising a Glycine at the amino terminus position of the peptide (SEQ ID No: 1). *Shimkets* teach nucleic acid encoding the peptide (e.g. SEQ ID No: 3), and vectors and host cells comprising the nucleic acid (§ 5.2). *Shimkets* also teach the vectors could be used as a therapeutic agent in a pharmaceutical carrier in gene therapy (§ 5.3.2) and delivered via liposome. Accordingly, *Shimkets* anticipate instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Shimkets* (US 6,013,630), in view of *Nicolaas et al* (Pharm Res 1996;13:1686-92).

Shimkets teach a pharmaceutical composition comprising a nucleic acid sequence encoding a natriuretic hormone peptide comprising a Glycine at the amino terminus position of the peptide (SEQ ID No: 1). *Shimkets* does not teach the composition further comprises a chitosan.

Nicolaas remedy the deficiency by establishing it was well known in the art before instant priority date that chitosans could enhance small peptide drug delivery (e.g. the abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Shimkets* by simply including chitosan for NHP peptide delivery as taught by *Nicolaas* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because of enhanced delivery efficiency. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30Am to 7pm Monday through Thursday, Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

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*/Q. JANICE LI/
Primary Examiner,
Art Unit 1633*

GL

April 10, 2008